

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: SB 1116
 SPONSOR: Senator Webster
 SUBJECT: Health Care Delivery and Research
 DATE: December 30, 2003 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill creates the Florida Center for Universal Research to Eradicate Disease (CURED) within the Department of Health (DOH). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use, with the goal of finding cures for diseases. The center will be funded through private, state, and federal sources. The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives with recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida.

The bill establishes an advisory council for the center, which must meet at least annually. The council will consist of the members of the board of directors of the Florida Research Consortium and 17 representatives of organizations named in the bill which support research and public awareness regarding diseases.

The bill amends s. 215.5602, F.S., which creates the James and Esther King Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis, and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires the program to give priority to research to prevent or cure disease.

The bill establishes the Florida Cancer Research Cooperative for the purpose of making Florida a world-class center for cancer research. The bill authorizes a not-for-profit corporation, acting as an instrumentality of the Florida Dialogue on Cancer, to govern the affairs of the cooperative. A 25-member board of directors will manage the affairs of the not-for-profit corporation. The cooperative must issue an annual report containing policy and funding recommendations

regarding cancer research capacity in Florida. The cooperative must develop and centralize the processes and shared services for expanding cancer research in Florida and must work in concert with the Florida Center for Universal Research to Eradicate Disease.

The bill establishes the Florida Public Health Foundation, Inc., in law, for the purpose of disseminating biomedical research breakthrough findings and promoting health awareness in Florida. The corporation must be established as a not-for-profit entity qualifying under section 501(c)(3) of the Internal Revenue Code. The corporation's duties will include procuring funds necessary for accomplishing the purpose and mission of the corporation. The affairs of the not-for-profit corporation will be managed by an executive director appointed by a board of directors, as specified in the bill. The corporation, in consultation with DOH and the Florida Center for Universal Research to Eradicate Disease, must facilitate communication between biomedical researchers and health care providers each month according to the health awareness schedule established by the Florida Public Health Foundation, Inc.

The Department of Health and the Florida Health Awareness Corporation must coordinate monthly health awareness campaigns with national, state, and local health care organizations and government entities targeting a wide range of the public. The awareness campaigns must include the provision of educational information about preventing, detecting, treating, and curing specified diseases or conditions.

This bill amends s. 215.5602, F.S., and creates five unnumbered sections of law.

II. Present Situation:

Coordination of Biomedical Research

Biomedical research contributes ultimately to the health of a population, and biomedical discoveries and the resultant products or treatments contribute to the economy of the area where they are produced. For both health and economic reasons, governments have an interest in furthering the work of biomedical researchers and in helping researchers collaborate and share resources. A number of states have initiatives to coordinate cancer research. Some state governments, as well as private foundations and companies, are addressing the needs of researchers who are conducting stem cell research.

Stem Cell Research

Stem cells are cells that have the ability to divide for infinite periods in culture. They give rise to specialized cells. Research involving stem cells shows the possibility of treating diseases and conditions such as Alzheimer's and Parkinson's diseases, spinal cord injury, stroke, burns, heart disease, and arthritis. The possibility that an organ could be grown from stem cells has implications for tremendous changes in organ transplants.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of

harvesting the stem cells is considered immoral by many because the embryo is killed. In August 2001, President Bush announced that he would allow federal funding of research using the 60 existing stem cell lines. Thus federal funds will not pay for stem cell research that involves the destruction of human embryos.

In November 2001, President George W. Bush created The President's Council on Bioethics "to advise the president on issues that may emerge as a consequence of advances in biomedical science and technology" (Executive Order 13237). In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

The Emerging Technology Commission

Under s. 240.72, F.S., the "Florida Technology Development Act," the Emerging Technology Commission is a commission created within the Governor's Office for the purpose of guiding the establishment of centers of excellence within, and in collaboration with Florida's universities.

ITFlorida and The Florida Research Consortium

ITFlorida is a private umbrella organization comprised of both public and private technology leaders for high-tech in Florida. ITFlorida's stated mission is to make Florida a leader in high tech advancement, providing guidance to the state on technology issues and initiatives, guiding the Governor, the Legislature and Enterprise Florida on the strategic technology direction and initiatives of the state and working to ensure the successful integration of technology infrastructure statewide.

The Florida Research Consortium, an affiliated entity of ITFlorida, is governed by a board of high-tech industry leaders and university heads whose mission is to advise the Legislature and Office of the Governor on strategic policy initiatives for expanding and strengthening Florida's high-tech industries. The consortium aims to identify specific disciplines in science and technology where Florida has the greatest potential to achieve economic and academic successes –and to promote collaboration between academic and industrial researchers, scientists and engineers.

Enterprise Florida, Inc.

Enterprise Florida, Inc., created under part VII of ch. 288, F.S., is a partnership between Florida's business and government leaders and is the principal economic development organization for the State of Florida. The organization's mission is to increase economic opportunities for all Floridians by supporting the creation of quality jobs, a well-trained workforce and globally competitive businesses. It pursues its mission in cooperation with its statewide network of economic development partners.

BioFlorida

BioFlorida's mission is to promote biotechnology and related science in Florida by creating a favorable business and legislative environment; to provide the platform for business, academia and government to work jointly to support and encourage development of existing companies in the state and to attract new business and organizations to Florida.

The Florida Medical Foundation

The Florida Medical Foundation is the Florida Medical Association's philanthropic organization for medical education, research, community service and physician support programs. The foundation emphasizes support for physicians at all stages of their professional careers. The foundation has a current project relating to doctor patient communications as a way of addressing the problem of low health literacy among patients.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that improve the health and longevity of patients. The industry invested more than \$30 billion in 2001 in discovering and developing new medicines. PhRMA companies are involved in the search for new cures.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state will use funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of scientific merit, as determined by an open, objective peer-review process. The council is required to submit a progress report to the Governor, Secretary of the Department of Health, President of the Senate, and Speaker of the House of Representatives by February 1 of each year.

The Florida Dialogue on Cancer

The Florida Dialogue on Cancer (FDOC) is a collaboration of Florida leaders of hospitals, research centers, universities, professional medical groups, community-based organizations, private business groups, as well as government officials. FDOC is an initiative designed to expand the state's capacity to reduce the incidence and mortality rates of cancer. The goals of FDOC are to:

- Create a coalition that speaks with one voice on major statewide cancer issues for Florida;
- Enhance and promote Florida's capacity to conduct cancer research, professional education, clinical trials and treatment programs; and
- Identify and promote the replication of best practices in providing access to cancer prevention, education, screening, diagnosis, and treatment programs for all Floridians and to reduce the disparities that exist.

The Florida Division of the American Cancer Society sponsors FDOC, which is based on the work of the National Dialogue on Cancer. Florida is the first state to establish a dialogue on cancer.

The Cancer Control and Research Advisory Council

The Cancer Control and Research Advisory Council (often referred to as the C-CRAB) was created by the 1979 Legislature. The council is located at the H. Lee Moffitt Cancer Center and Research Institute, Inc. Under s. 1004.435, F.S., the Council's mandate includes:

- Advising the State Board of Education, the Secretary of Health and the Legislature, on cancer control and research issues.
- Developing the Florida Cancer Plan.
- Recommending to the Secretary of Health a plan for the care and treatment of cancer patients and make recommendations for the operation of cancer units in hospitals and clinics in Florida.
- Allocating funds, if available, for research and demonstration projects that address the priorities of the Florida Cancer Plan.

The Florida Public Health Foundation, Inc.

The Florida Public Health Foundation, Inc., is a Florida non-profit corporation operating within the exemption established by 26 U.S.C.A., Internal Revenue Code, Section 501(c)(3). The purposes of the foundation are to engage in charitable programs dedicated to improving the health of Florida citizens and to conduct educational programs for those working and interested in public health.

Health Awareness Campaigns

The Department of Health conducts public information campaigns on diseases and other health risks to the extent that funding is available. The department implements a comprehensive, statewide tobacco control program that focuses on young people with the goal of preventing initial use of tobacco and reducing tobacco use. General information about diseases and health conditions is available on the department's web site (<http://www.doh.state.fl.us>).

III. Effect of Proposed Changes:

Section 1. Creates the Florida Center for Universal Research to Eradicate Disease (CURED) within the Department of Health (DOH). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding

opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees will be required to cover, or obtain sponsorship for, the costs of their attendance.

The center must:

- Encourage clinical trials in Florida on research that holds promise of curing a disease or condition;
- Facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, placentas and cord blood;
- Facilitate the formation of partnerships between Florida researchers and institutions in other states and countries where research with rare plants or animals could lead to cures;
- Encourage Florida's agricultural colleges and agricultural businesses to be active in the search for cures and the provision of public information about disease prevention;
- Facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur in developing countries; and
- Encourage the discovery and production in Florida of vaccines that prevent disease.

The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers. If the center determines that there is a need for increased donation of human tissue, it must notify hospitals licensed under ch. 395, F.S., that have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. The hospitals must then implement programs that encourage voluntary donations of cord blood or other needed tissues.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced by the Department of Health to a private entity or state university.

An advisory council, established within the center, must meet at least annually. The council will consist of the members of the board of directors of the Florida Research Consortium and at least one representative from:

- The Emerging Technology Commission.
- Enterprise Florida, Inc.
- BioFlorida.
- The Florida Biomedical Research Advisory Council.
- The Florida Medical Foundation.
- Pharmaceutical Research and Manufacturers of America.
- The Florida Tri-Agency Coalition on Smoking and Health.
- The Florida Cancer Research Cooperative, Inc.
- The American Cancer Society, Florida Division, Inc.
- The American Heart Association.
- The American Lung Association of Florida.
- The American Diabetes Association, South Coastal Region.
- The Alzheimer's Association.
- The Epilepsy Foundation.
- The National Parkinson's Foundation.
- The Florida Public Health Foundation, Inc.
- Scripps Florida, or the entity formed by the Scripps Research Institute in Florida.

Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

Section 2. Amends s. 215.5602, F.S., which creates the James and Esther King Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis, and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires the program to give priority to research to prevent or cure disease. The Biomedical Research Advisory Council must submit a copy of its annual report to the Florida Center for Universal Research to Eradicate Disease, as well as to the Governor, the Secretary of Health, the President of the Senate and the Speaker of the House of Representatives.

Section 3. Establishes the Florida Cancer Research Cooperative for the purpose of making Florida a world-class center for cancer research. The bill authorizes a not-for-profit corporation, acting as an instrumentality of the Florida Dialogue on Cancer, to govern the affairs of the cooperative. The cooperative may create not-for-profit corporate subsidiaries to fulfill its mission, and those subsidiaries could receive, hold, invest, and administer property and any monies acquired from private, local, state, and federal sources as well as technical and professional income from the mission-related activities of the cooperative.

A board of directors will manage the affairs of the not-for-profit corporation. The 25-member board will be comprised of:

- The Secretary of Health, or his or her designee,
- The Chief Executive Officer of the H. Lee Moffitt Cancer Center or his or her designee,

- The President of the University of Florida Shands Cancer Center, or his or her designee,
- The Chief Executive Officer of the University of Miami Sylvester Comprehensive Cancer Center, or his or her designee,
- The Chief Executive Officer of the Mayo Clinic, Jacksonville, or his or her designee,
- The Chief Executive Officer of the American Cancer Society, Florida Division, or his or her designee,
- The President of the American Cancer Society, Florida Division Board of Directors, or his or her designee,
- The President of the Florida Society of Clinical Oncology, or his or her designee,
- The Chief Executive Officer of Enterprise Florida, Inc., or his or her designee,
- Three representatives from large Florida hospitals or institutions which treat a large volume of cancer patients, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives,
- Three representatives from community-based, statewide organizations serving populations that experience cancer disparities, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives,
- One member of the House of Representatives, to be appointed by the Speaker of the House of Representatives,
- One member of the Florida Senate, to be appointed by the President of the Senate,
- Three university presidents, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives, and
- Five representatives from other statewide public health organizations whose missions include public education and the eradication of cancer, three of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives.

Appointments made by the Senate President and House Speaker will be for 2-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor will be for 2-year terms, and the Governor may reappoint members.

The cooperative must issue an annual report to the Governor, President of the Senate, the Speaker of the House of Representatives, and the Florida Center for Universal Research to Eradicate Disease by December 15 of each year. The report must contain policy and funding recommendations regarding cancer research capacity in Florida.

Section 4. Establishes the mission and duties of the Florida Cancer Research Cooperative. The cooperative must develop and centralize the processes and shared services for expanding cancer research in Florida through:

- Support through bioinformatics to create a cancer informatics infrastructure that enhances information and research exchange;
- Technical coordination, business development, and support of intellectual property;
- Development of a statewide cancer clinical trials network; and
- Other activities to support multidisciplinary research.

The cooperative must work in concert with the Florida Center for Universal Research to Eradicate Disease.

Section 5. Establishes the Florida Public Health Foundation, Inc., in law, for the purpose of disseminating biomedical research breakthrough findings and promoting health awareness in Florida. The corporation's mission will include disseminating information about innovative biomedical research and clinical trials in Florida, as well as making Floridians and their treatment providers aware of specified diseases and conditions and of available methods of preventing, diagnosing, treating, and curing those diseases and conditions.

The corporation must be established as a not-for-profit entity qualifying under section 501(c)(3) of the Internal Revenue Code, and is authorized to receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal sources, as well as technical and professional income generated, or derived, from the mission-related activities of the corporation.

The corporation's duties will include procuring funds necessary for accomplishing the purpose and mission of the corporation. The corporation must complement, supplement, and enhance the missions of the various organizations, entities, and departments represented on its board by serving as the lead overall public health awareness corporation in the state.

The affairs of the not-for-profit corporation will be managed by an executive director appointed by a board of directors consisting of:

- The Secretary of the Department of Health or his or her designee.
- A former member of the Florida Senate appointed by the President of the Senate,
- A former member of the Florida House of Representatives appointed by the Speaker of the House of Representatives,
- A representative of the American Heart Association,
- A representative of the American Cancer Society, Florida Division, Inc.
- A representative of the American Lung Association of Florida,
- A representative of the American Diabetes Association, South Coastal Region,
- A representative of the Alzheimer's Association,
- A representative of the Epilepsy Foundation,
- A representative of the National Parkinson's Foundation,
- A representative of the March of Dimes, Florida Chapter,
- A representative of the Arthritis Foundation, Florida Chapter,
- A representative of the American Liver Foundation,
- A representative of the Florida Council for Behavioral Healthcare, Inc.,
- A representative of the Florida Alcohol and Drug Abuse Association, Inc.,
- A representative of Pharmaceutical Research and Manufacturers of America,
- A representative of the Florida Public Health Association,
- A public health academician selected by the state health officer,
- A representative of the Florida Academy of Family Physicians, and
- 3 consumers who have demonstrated an interest in promoting public health, appointed by the Public Health Association.

Members of the board of directors will serve for 2-year terms and shall serve without compensation.

The corporation, in consultation with DOH and the Florida Center for Universal Research to Eradicate Disease, must facilitate communication between biomedical researchers and health care providers each month according to the health awareness schedule established by the Florida Public Health Foundation, Inc. The corporation and DOH must enter into partnerships with providers of continuing education for healthcare practitioners to ensure that practitioners are aware of the most recent and complete diagnostic and treatment tools. The corporation must provide an annual report concerning its activities and finances to the Florida Center for Universal Research to Eradicate Disease, the Governor, Senate President, and House Speaker.

Section 6. Requires the Department of Health and the Florida Health Awareness Corporation to coordinate monthly health awareness campaigns with national, state, and local health care organizations and government entities targeting a wide range of the public, including: parents, teachers, and other school employees; students in 4th through 12th grade, colleges, and universities; state agency employees; county and local government employees; patients of county health departments; Medicaid recipients; health care professionals and providers; and the public in general.

The awareness campaigns must include the provision of educational information about preventing, detecting, treating, and curing specified diseases or conditions. Additional diseases and conditions which impact the public health may be added. The following diseases and conditions must be included in a public awareness campaign during at least one month in any 24-month period:

- Cancer, including breast, prostate, cervical, ovarian, colorectal, and skin cancer as well as leukemia;
- Heart disease;
- Stroke;
- Lung disease, including asthma and smoking-related diseases;
- Neurological disorders and disease, including Alzheimer's disease, Parkinson's disease, and Epilepsy;
- Gastrointestinal disease;
- Kidney disease;
- Diabetes;
- Liver disease;
- Autoimmune disorders;
- Birth defects and prenatal care;
- Obesity and malnutrition;
- Sexually transmissible diseases;
- Hepatitis A, B, and C;
- Arthritis;
- Vaccine-preventable diseases;
- Infectious diseases including HIV/AIDS;
- Substance abuse; and
- Mental illness.

The health awareness campaigns must be funded by the Florida Public Health Foundation, Inc., and the Florida Department of Health to the extent that funds are available from public and private sources. Health awareness information must be disseminated through all available methods, including print, audio, visual, and electronic media.

Section 7. Provides that the bill will take effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
